TRACON Pharmaceuticals Announces Publication of Phase 1b Results for TRC105 in Combination with Inlyta® in Patients with Advanced or Metastatic RCC

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Data Published in Peer-Reviewed Journal, The Oncologist

SAN DIEGO, Sept. 10, 2018 (GLOBE NEWSWIRE) -- TRACON Pharmaceuticals (NASDAQ:TCON), a clinical stage biopharmaceutical company focused on the development and commercialization of novel targeted therapeutics for cancer, wet age-related macular degeneration and fibrotic diseases, today announced the publication of results from a Phase 1b clinical trial combining TRC105 with Inlyta® (axitinib) in patients with advanced or metastatic renal cell carcinoma (RCC). Dr. Toni Choueiri of the Dana Farber Cancer Institute and colleagues published these results in the peer-reviewed journal, *The Oncologist* (Epublication ahead of print is available at PubMed.gov through PubMed ID number 30190302), and Dr. Andrew Hahn of the Huntsman Cancer Institute and co-authors published an accompanying editorial (Epublication ahead of print is available at PubMed.gov through PubMed ID number 30139834). These data were previously presented at the European Society for Medical Oncology (ESMO) 2016 Congress in Copenhagen, Denmark.

The open-label dose escalation and expansion Phase 1b study enrolled a total of 18 patients (17 of whom were evaluable for response) who had received at least one prior line of therapy with a VEGF receptor tyrosine kinase inhibitor (VEGFR TKI). The median number of prior therapies in the group was three, with a range of one to six. All patients in the trial received a combination of TRC105 and Inlyta. The data are summarized in the table below.

Summary of Phase 1b Results for TRC105-Inlyta Combination in RCC

Patients	ORR	Stable Disease	Overall Disease Control	Median PFS	Median PFS in Clear Cell RCC Subset (n=12)
N = 17	29% (5/17)	59% (10/17)	88% (15/17)	11.3 months	11.3 months

For comparison, in a separate trial, the objective response rate (ORR) seen in the large subgroup of VEGFR TKI-refractory patients treated with Inlyta (n=194) in the Inlyta AXIS Phase 3 study in second-line clear cell RCC patients was 11.3%, and median progression-free survival (PFS) was 4.8 months.

The publication also notes that plasma levels of TGF-β receptor 3 (betaglycan) at baseline were significantly higher in patients who experienced a partial response, while levels of osteopontin were significantly lower at baseline for patients that achieved a partial response. Both markers correlated with time on study and their potential prognostic value are being investigated in the ongoing Phase 2b TRAXAR study. TRACON's Phase 2b TRAXAR clinical trial of TRC105 in combination with Inlyta completed enrollment of 150 patients with advanced or metastatic RCC in Q3 2017 and top-line data are expected to be available in December 2018.

About the TRAXAR Phase 2b Clinical Trial in RCC

The Phase 2b TRAXAR clinical trial is a multicenter, open-label, randomized clinical trial of TRC105 in combination with Inlyta versus Inlyta in patients with advanced or metastatic RCC. The primary endpoint of the Phase 2b study is progression-free survival. Patients may have also failed one prior mTOR inhibitor and one prior immunotherapy. For additional information on this clinical trial, please visit www.clinicaltrials.gov, identifier NCT01806064.

About Carotuximab (TRC105)

TRC105 is a novel, clinical stage antibody to endoglin, a protein overexpressed on proliferating endothelial cells that is essential for angiogenesis, the process of new blood vessel formation. TRC105 is currently being studied in a pivotal Phase 3 trial in angiosarcoma and multiple Phase 2 clinical trials, in combination with VEGF inhibitors, as well as in a Phase 1 trial with Opdivo. TRC105 has received orphan designation for the treatment of soft tissue sarcoma in both the U.S. and EU. The ophthalmic formulation of TRC105, DE-122, is currently in a randomized Phase 2 trial for patients with wet AMD. For more information about the clinical trials, please visit TRACON's website at www.traconpharma.com/clinical_trials.php.

About TRACON

TRACON develops targeted therapies for cancer, ophthalmic and fibrotic diseases. The Company's clinical-stage pipeline includes: TRC105, an endoglin antibody that is being developed for the treatment of multiple cancers; DE-122, the ophthalmic formulation of TRC105 that is being developed in wet AMD through a collaboration with Santen Pharmaceutical Company Ltd.; TRC102, a small molecule being developed for the treatment of lung cancer and glioblastoma; and TRC253, a small molecule being developed for the treatment of prostate cancer. To learn more about TRACON and its product candidates, visit TRACON's website at www.traconpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements, including statements regarding TRACON's plans and timing with respect to on-going clinical trials, and other development plans and potential benefits of TRACON's product candidates. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include, but are not limited to, the fact that initial clinical trial results or results from prior studies may not be consistent with subsequent results, TRACON's and others' ability to identify and enroll patients in on-going and planned clinical trials, potential delays in completing on-going clinical trials, whether TRACON's product candidates will be shown to be safe and effective in subsequent studies, and TRACON's and others' ability and willingness to fund additional clinical development of TRACON's product candidates. For a further description of these and other risks facing TRACON, please see the risk factors described in TRACON's filings with the United States Securities and Exchange Commission, including those factors discussed under the caption "Risk Factors" in those filings. Forward-looking statements speak only as of the date of this press release and TRACON undertakes no obligation to update or revise these statements, except as may be required by law.

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